Evidence-Based Practice Center Systematic Review Protocol

Project Title: Childhood Obesity Prevention Programs: A Comparative Effectiveness Review and Meta-Analysis

I. Background and Objectives for the Systematic Review

Background

The childhood obesity epidemic

Scope of the problem: Childhood obesity is a serious health problem in the United States.¹ Data from the 2007-2008 National Health and Nutrition Examination Survey indicated approximately 17% of US children and adolescents (ages 2-19) years are obese.² Obesity prevalence increased from 5% to 10.4% (children aged 2-5 years); 6.5% to 19.6% (children aged 6-11 years); and 5% to 18.1% (adolescents aged 12-19 years) between 1976-1980 and 2007-2008.²³ Some minority groups such as African Americans, Hispanic, and Native Americans, and low-income groups are at higher risk of obesity.⁴⁵ However, the patterns are complicated, and not all low-income or minority groups are at high risk, and the relationship between obesity and social-economic status (SES) has changed over time in the US.⁴⁶ Asian Americans have a lower prevalence of obesity than other ethnic groups, while higher income African American girls were more likely to be overweight than their lower income counterparts. The inverse relationship between obesity and SES is seen only in white females. However, SES factors only explain a very small portion of the variations in BMI (e.g., 1-2%).

Complex causes of obesity: Obesity is the result of a large number of biological, behavioral, social, environmental and economic factors and the complex interactions between them that promote a positive energy balance. At present, how these factors affect children and contribute to the disparities in obesity prevalence between population groups in the US remain poorly understood. Nevertheless, a growing body of research suggests that many factors interact including: individual factors (e.g., genetics, nutrition knowledge and attitude, body weight image), home influences (e.g., parenting, food served at home, parental weight status), school factors (e.g., nutrition service, curriculum including physical activity, annual BMI measure), those in the local community (e.g., food environment, crime rate), and at the regional and national levels (e.g., built environment, economic factors such as food prices, and food assistance programs). They contribute to obesogenic environments and affect children's weight. A number of leading health organizations and expert panels (e.g., the World Health Organization⁷ and an Institute of Medicine expert panel⁸¹¹⁵¹³¹⁵ #54) have recommended that multiple and comprehensive interventions are needed to fight the growing obesity epidemic.⁹
Measurement of adiposity and classification of childhood obesity: Changes in adiposity due to the intervention in related studies will be our key outcomes to assess in the systematic review. Various measures have been used in the field to assess adiposity and childhood obesity. Although BMI has been widely used in the classification of obesity in adults and children, it remains controversial regarding what measures and what cut points are most appropriate. Different sex-age specific BMI percentile cut points have been used in the US and worldwide. In the US, two sets of 85th (for 'overweight') and 95th percentiles (for 'obesity') have been used, with the recent one published by the CDC in 2000. In general, the values of the two sets percentile are similar, but they were developed based on different data and growth curve fitting techniques. In addition, different terms have been used. Before the mid-2000's, key health organizations including the WHO recommended use of the term of 'at risk of overweight' for 'overweight', and 'overweight' for 'obesity'. Additionally, BMI is an indirect measure of adiposity, and thus has several limitations. Other measures, such as percentage of body fat measured via direct measures such as dual-emission X-ray absorptiometry (DXA), waist circumference, waist-to-height ratio, skinfold thickness and related cut points, have been increasingly used to assess adiposity and define obesity, both in adults and children. The evidence is mixed on the correlation between direct and indirect measures of adiposity, particularly in among different age groups, the morbidly obese and individuals with above-average lean muscle mass.

Consequences of childhood obesity: Childhood obesity has many intermediate- and long-term health consequences. Overweight children and adolescents are at greater risk for health problems compared to their normal weight counterparts. Overweight children and adolescents are more likely to become obese as adults. Obesity is a risk factor for a variety of chronic conditions, including type 2 diabetes, hypertension, high cholesterol, stroke, heart disease, nonalcoholic fatty liver disease, certain cancers, and arthritis. Obesity increases mortality as well. It is estimated that 70% of diabetes cases in the U.S. are caused by excess weight. Obese children and adolescents are more likely to have adverse health conditions, such as cardiovascular-, metabolic, and psychosocial outcomes. The other reported health consequences of childhood obesity include eating disorders, and mental health issues such as depression and low self-esteem.

In addition, overweight and obesity and their associated health problems have a significant economic impact on the U.S. health care system. Childhood obesity in the US is estimated to cost $11 billion for children with private insurance and $3 billion for children on Medicaid. The health care costs of an overweight or obese child is roughly 3 times higher than the average child as they are 2-3 times more likely to be hospitalized and are far more likely to be diagnosed with health disorders than non-obese children. Further, once developed, obesity is difficult to treat (e.g., due to the 'set point theory'). Therefore, it is important to help the public develop life-long healthy lifestyles and prevent obesity at young ages.

Interventions, controversy or uncertainty about the topic
We chose to organize the KQs for this review by settings rather than by the specific interventions (e.g., eating, physical activity or knowledge) based on a number of considerations:
1) This is frequently how this research is organized (e.g., as indicated by some published reviews, some focused on school-based interventions, others on environment- and policy based interventions);

2) Interventions conducted in different settings differ in their supporting behavioral theories, and differ in who implements the programs once proven effective;

3) Setting-specific data will be more useful for end users such as policy makers, parents, school administrators, public health professionals, primary care providers, and child care administrators.

Also, it is important to highlight the distinction between prevention (often called "intervention" in the childhood obesity research field) and treatment. This review will focus on prevention; it will not review the targeted treatment of overweight or obese children, which has been reviewed in another recent AHRQ report that included studies of weight loss and studies of weight stabilization in that population.28 The main goal of most childhood obesity prevention programs is to prevent non-overweight children from becoming overweight or obese, while the primary objective of obesity treatment programs is for pediatric patients to lose weight. We acknowledge that programs designed for obesity prevention may also help overweight or obese children lose weight or stabilize their weight.

Various interventions for childhood obesity prevention and management have been developed and assessed in the US and many other countries. These include interventions conducted in different settings (eg, school-, family-, clinic-, community- and policy- based ones), with various targeted outcomes (eg, to promote healthy eating or increased physical activities or reduced sedentary behaviors such as TV time), developed based different behavioral theories, and/or based on different intervention approaches (eg, through changes in individuals' (children's or their care providers') psychosocial factors such as knowledge, attitude and belief or changes in the physical environment such as food provided in the school or work environment).

However, these studies have provided mixed results. Some reviews have examined intervention studies related to childhood obesity prevention. We have identified over 20 systematic reviews of childhood obesity prevention. We found that most focused on school-based interventions, and have a number of limitations, including: a) they did not include interventions conducted in other settings, such as home, community, built-environment, and primary care; b) they only included selected outcomes such as BMI and obesity rates, but not other important outcome variables; c) they were not comprehensive. Many were region specific, that is, some only focused on China, Europe, UK, and the US, respectively; and d) few did any quantitative pooling (i.e., meta-analysis). In addition, many of these reviews are limited by many other shortcomings such as inappropriate management of study heterogeneity, lack of randomized, controlled interventions; lack of objective outcome measures, poor methodology in the primary studies, lack of consistent research themes, and lack of quality control. Some new studies have been published since the publication of these reviews. Our proposed review will use more vigorous approaches to help overcome the limitations of previous reviews.

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The majority of childhood obesity prevention studies are school-based, while other types of prevention programs such as those in other various settings like primary care settings, child care centers, community centers, churches, as well as new policy initiatives such as regulations of vending machines in schools, annual BMI screening in schools, and food marketing targeting at children have also been assessed in recent years. A growing consensus in the field is that comprehensive intervention programs, those that involve multiple sectors in our society or that target multiple factors affecting energy balance behaviors, are needed to fight the obesity epidemic in the US. In summary, there are many questions that the previous reviews did not answer. Additionally, this field is rapidly expanding and many relevant studies have been published in recent years. Our analysis and inclusion of the different settings and diverse interventions along with a rigorous meta-analysis of the findings will make unique contribution to the literature.

Expected use of the comparative effectiveness review

Potential end-users of this proposed evidence review will include health professionals and their patients, researchers, and policy makers, including those engaged at the local and federal government levels in prevention. The results may inform decision making among key stakeholders, including health professionals, patients and families, researchers and policymakers. This report will also help support initiatives for fighting the childhood obesity epidemic. We expect that this report will provide a more solid evidence-base and more vigorous methodologies in systematic review and meta-analysis compared to previously published reviews based on vigorously developed study protocol including through a systematic review of all relevant studies that meet our inclusion criteria and careful meta-analysis of the related findings from individual studies.

Objectives

We aim to compare the effectiveness of obesity intervention programs for children and adolescents conducted in the United States and other developed countries.

II. The Key Questions
The key questions and scope were revised with input from a technical expert panel and public commentary. In summary:

1. All key questions were re-worded to reflect that this systematic review will focus on prevention of obesity or overweight in children: “What is the comparative effectiveness of [add intervention setting here] for the prevention of obesity or overweight in children?

2. Key questions 5 (community setting intervention) and 6 (environment setting intervention) were combined to read: new KQ5: What is the comparative effectiveness of community-based or environment interventions for the prevention of obesity or overweight in children? Definitions of terms were enhanced.

3. Follow-up period of interventions in all settings except school-based settings and multi-settings that include school-based settings remains 1-year. The required follow-up period for school-based interventions was changed to 6-months to accommodate the thinking
that some school-based interventions will only be implemented and measured within the academic year.

Summary of Key Questions

KQ1: What is the comparative effectiveness of school-based interventions for the prevention of obesity or overweight in children?
KQ2: What is the comparative effectiveness of home-based interventions for the prevention of obesity or overweight in children?
KQ3: What is the comparative effectiveness of primary care-based interventions for the prevention of obesity or overweight in children?
KQ4: What is the comparative effectiveness of child-care setting-based interventions for the prevention of obesity or overweight in children?
KQ5: What is the comparative effectiveness of community-based or environment-level interventions for the prevention of obesity or overweight in children?
KQ6: What is the comparative effectiveness of consumer health informatics applications for the prevention of obesity or overweight in children?
KQ7: What is the comparative effectiveness of multi-setting interventions for the prevention of obesity or overweight in children?

Population(s)

- All children between the ages of 2 and 18 years old, regardless of BMI classification.

Interventions (and selected examples)

- Key Question 1: school-based interventions, including
  - nutrition, diet, and healthy eating
  - physical education
  - school curricula
  - vending machines and availability of snacks; cafeteria foods
  - policy (e.g., federal, state, local government and school's own policies that may affect students' eating behavior and physical activity in schools. Take eating behavioral as an example, these can include those that may affect what food will be provided in school cafeteria and those that influence students nutrition knowledge.

- Key Question 2: home-based interventions, including
  - nutrition, diet, and healthy eating
  - parenting styles/education
  - policy

- Key Question 3: primary care-based interventions, including
  - patient counseling
  - referrals to nutritionists
  - policy (e.g. federal, state, and local government and policies related to the practice in the primary care setting)
• Key Question 4: child care-based interventions, including
  o menu changes
  o physical activity
  o policy (e.g., federal, state, local government and child-care organizations' own policies that may affect students’ eating behavior and physical activity, and these may include how and what food may be provided and facility standards that may affect children's physical activity)

• Key Question 5: community-based or environment-level interventions, including
  o physical activity
  o farmer’s markets
  o community gardens
  o cooking lessons
  o green space, parks and sidewalks
  o food store accessibility
  o access to healthy food choices
  o policy (e.g. federal, state, and local government or other organizations (eg, chain food stores) policies that may affect foods and physical activity in the local communities such as regulation on marketing, community parks, food and fitness outlets and facilities)

• Key Question 6: consumer health informatics applications, including
  o web-based interventions
  o cell phone-based interventions
  o policy(e.g. federal, state, and local government policies related to food and physical activity related products or services provided via internet and cell phone)

• Key Question 7: multi-setting interventions, including
  o Any combination of the above interventions

NOTE: A policy is typically described as a principle or rule to guide decisions and achieve rational outcome, and it is set for a group or an organization to follow. Regarding polices for each setting, these many related to government and the organizations' related ones that may affect children' eating and physical activity, and thus may affect weight outcomes.

Comparisons
• No intervention
• Usual care or other interventions within or across settings
NOTE: We will compare the intervention group vs the control group (ie, those who did not receive intervention or received usual care or other interventions) within each study and then across studies within the same setting (eg, schools or child care centers).

Outcomes
- Primary outcomes
  - change in prevalence of obesity
  - change in BMI or BMI distribution in the population
  - changes in adiposity or other weight measures
- Intermediate outcomes
  - nutrition knowledge, attitudes, beliefs, and diet and PA self-efficacy
  - food purchasing behaviors
  - dietary intake
  - food access
  - physical activity
  - sedentary behavior
- Adverse effects
  - eating disorders
  - psychosocial outcomes
  - impact on growth and development
  - injury
  - cost
- Obesity-related clinical outcomes
  - Cardiovascular outcomes
  - Metabolic outcomes
  - Psychosocial outcomes

Timing
- Outcome assessment must be at least 1-year from the baseline assessment for key questions 2 through 7 (if it does not include school-based interventions). Outcome assessment must be at least 6 months from the baseline assessment for key question 1, school-based interventions. This also applies to multi-setting interventions (KQ7) that include school-based interventions.

Setting
- Schools, home, primary-care clinics, child-care settings, or community organizations, environmental-level interventions, or across these settings.
III. Analytic Framework (see alternative text in separate document)

Figure 1. Analytic Framework for Comparative Effectiveness of Childhood Obesity Intervention Programs

Adverse effects of intervention
- Burden of intervention
- Eating disorders
- Psychosocial outcomes, e.g., stigma
- Impact on growth and development
- Injury
- Cost
- Other adverse effects

Intermediate Outcomes
- Nutrition Knowledge, Attitudes, Beliefs (child and caregivers)
- Food purchasing Behaviors (child and caregivers)
- Dietary Intake (energy, nutrients, foods)
- Food access
- Physical Activity
- Sedentary behavior

Primary Outcomes
- Change in overweight and obese status
- Prevalence of overweight and obese
- Body mass index (BMI) or other adiposity measures

Obesity-related Clinical Outcomes
- Cardiovascular outcomes
- Metabolic outcomes
- Psychosocial outcomes, e.g., self-esteem, health-related quality of life (HRQOL)

All children age 2-18 yrs

Settings
- KQ1 - School-based
- KQ2 - Home-based
- KQ3 - Primary care-based
- KQ4 - Child care-based
- KQ5 - Community-based or environment-level
- KQ6 - Consumer health informatics
- KQ7 - Multi-setting interventions

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IV. Methods

First, we will systematically search for evidence about the comparative effectiveness of childhood obesity intervention and prevention programs in various settings in children and adolescents aged 2-18 years conducted in the United States and other developed countries. In particular, we will identify the studies that meet our inclusion criteria. Next, we will abstract relevant information from the identified publications. Finally, we will conduct meta-analysis of the results from the published studies, and generate a research report.

A. Criteria for Inclusion/Exclusion of Studies in the Review.

Inclusion and exclusion criteria are provided in Table 1. All studies of obesity prevention in children conducted in high-income countries with at least one year of follow-up (or at least 6 months follow-up for school-based interventions) are eligible.

<table>
<thead>
<tr>
<th>Table 1. Inclusion and exclusion criteria</th>
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<tr>
<td><strong>Population and condition of interest</strong></td>
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<tr>
<td>□ Studies of children and adolescents aged 2-18 years old, regardless of BMI classification, are included</td>
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<td>□ Studies targeting only overweight or obese subjects will be excluded.</td>
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<td>□ Studies targeting subjects with diseases/chronic conditions (T2DM, CVD) will be excluded.</td>
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<tr>
<td><strong>Interventions</strong></td>
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<td>□ Studies that do not include an intervention aimed at obesity prevention or affecting energy-balance behaviors will be excluded.</td>
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<td>□ Studies that aim at weight loss (obesity treatment) will be excluded.</td>
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<tr>
<td><strong>Comparisons of interest</strong></td>
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<tr>
<td>□ Studies must compare the intervention to no intervention, usual care or other interventions within or across settings; or compare to prior interventions for natural experiment studies.</td>
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<tr>
<td><strong>Outcomes and Timing</strong></td>
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<tr>
<td>□ All studies must report changes or differences between the intervention and control groups in the prevalence of obesity or/and overweight, BMI or BMI distribution in the population, adiposity or other weight measures such as waist circumference or body fat.</td>
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<td>□ Outcome assessment must be at least 1-year after the baseline assessment for key questions 2 through 7 (if does not include school-based interventions).</td>
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<tr>
<td>□ Outcome assessment must be at least 6 months after the baseline assessment for key question 1 or for key question 7 that includes a school-based intervention.</td>
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<tr>
<td><strong>Type of study</strong></td>
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<td>□ Experimental, quasi-experimental interventions and natural experiments will be included.</td>
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<td>□ We will exclude studies with no original data (e.g., reviews, editorials,</td>
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We will exclude non-interventional studies (e.g., cross-sectional and cohort studies, case reports) although we will not require randomization.

We will exclude studies published only as abstracts.

We will exclude qualitative studies that do not provide quantitative information on an approach of interest and weight or adiposity, such as focus groups or directed interviews.

Pilot studies of an experimental design will be included.

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

We will search the following databases for primary studies: MEDLINE®, EMBASE®, PsychInfo, CINAHL, and the Cochrane Library. We will develop a search strategy for MEDLINE, accessed via PubMed, based on an analysis of the medical subject headings (MeSH) terms and text words of key articles identified a priori. The search strategy for MEDLINE can be found in Appendix A. We will not restrict the search by date or language. The titles will be reviewed first; next, the identified abstracts; then the full papers.

We will also review the reference lists of each included article, relevant review articles and related systematic reviews to identify articles that may have been missed by the database searches.

C. Data Abstraction and Data Management

The EPC research team uses DistillerSR (Evidence Partners, 2010), to manage the screening and review process. DistillerSR is a web-based database management program that manages all levels of the review process.

All applicable citations identified by the search strategies will be uploaded to the system and reviewed in the following manner:

i. Title screening: Each title will be screened by 2 independent reviewers for potential relevance to this project. This level of screening is liberal, requiring only one reviewer indicating that a title is potentially relevant for the title to progress to the next stage of review. In order for a title to be eliminated at this level, both reviewers must indicate that it is not relevant to this project. Liberal review will be used at this level to capture any title that might apply to the key questions.
ii. Abstract screening: Each abstract will be reviewed by 2 independent reviewers. Both reviewers must agree on whether or not an abstract is applicable to any of the key questions. If there is disagreement between the 2 reviewers they will be asked to review their answers and come to an agreement. Conflicts that cannot be resolved by the two original reviewers will be resolved by a third-party.

Relevant reviews, including systematic reviews and meta-analyses, will be tagged for a references list search.

iii. Full-text article screening: The review protocol for this level will be the same as for the abstract inclusion/exclusion level. Conflicts at this level will be resolved by a third-party senior reviewer.

iv. Data abstraction: Eligible articles will be sent for data abstraction. Forms to abstract details about the study design and conduct, the population, setting, country, sample sociodemographic characteristics, intervention approach(s) and outcomes are designed to answer the key questions. Note that we will try to collect contextual information such as about the population, setting, country. For example, for school-based intervention studies, we may collect information regarding in what country the study is conducted and if the school is in low-income community and about its student racial composition when such information is reported.

Each article will be serially abstracted first by a junior reviewer then by a senior reviewer. Articles referring to the same study will be abstracted on a single review form if reporting the same data or on separate forms if necessary with clear information that the results should be interpreted as from the same study. Data abstraction will be randomly quality checked by a third-party senior reviewer (investigator) to ensure that data is being abstracted accurately and thoroughly.

D. Assessment of Methodological Quality of Individual Studies

Article quality will be assessed using the Downs & Black quality assessment tool.\textsuperscript{30} For the RCTs and non-randomized studies, the overall study quality is assessed as:

- **Good** (low risk of bias). These studies had the least bias, and the results were considered valid. These studies adhered to the commonly held concepts of high quality, including the following: a clear description of the population, setting, approaches, and comparisons; sound study sample (eg, adequate sample size and appropriate characteristics of the sample); appropriate measurement of outcomes;
appropriate statistical and analytic methods and reporting; no reporting errors; a low dropout rate; and clear reporting of dropouts.

- **Fair.** These studies were susceptible to some bias, but not enough to invalidate the results. They did not meet all the criteria required for a rating of good quality because they had some deficiencies, but no flaw was likely to cause major bias. The study may have been missing information, making it difficult to assess limitations and potential problems.

- **Poor** (high risk of bias). These studies had significant flaws in design, implementation or report that might have invalidated the results. They had serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

E. Data Synthesis (mainly meta-analysis)

For each Key Question, we will create a set of detailed evidence tables containing all information abstracted from eligible studies. We will conduct meta-analyses when there is sufficient data (at least 5 studies of the same design) and studies are sufficiently homogenous with respect to the population characteristics, intervention, comparison, outcome, and timing. The time points of interest for outcome changes are: 1 year, 2 years, 3 years and more than 3 years if available in multiple studies. We expect to examine the intermediate outcomes such as dietary intakes and physical activity as well as nutrition related knowledge in those studies that also report the primary outcomes.

For studies amenable to pooling with meta-analyses, we will calculate pooled mean differences, risk differences or relative risks using a DerSimonian and Laird random effects model. We will identify statistical heterogeneity between the intervention studies in all the meta-analyses using: (1) a chi-squared test with a significance level of alpha less than or equal to 0.10, and (2) an I-squared statistic with a value greater than 50% indicating substantial heterogeneity. We conduct sensitivity analyses by omitting one study at a time to assess the influence of any single study on the pooled estimate. For all meta-analyses, we will conduct formal tests for publication bias using Begg’s and Eggers tests including evaluation of the asymmetry of funnel plots for each comparison of interest. All meta-analyses will be conducted using STATA (Intercooled, version 11, StataCorp, College Station, TX).

When we are unable to pool studies, we will calculate and display the individual mean differences, risk differences or relative risks with 95% confidence.

Subgroup analysis: We will conduct subgroup meta-analyses when there are sufficient data (at least 5 studies of the same design or outcome), eg, by the
population characteristics (eg, country of study, SES, age), intervention (eg, education, change in the environment, or policy), outcome (eg, weight related outcomes or behavioral ones such as diet and physical activity).

F. Grading the Evidence for Each Key Question

At the completion of the review, we will grade the quantity, quality and consistency of the best available evidence addressing Key Questions 1 – 7 by adapting an evidence grading scheme recommended by the Methods Guide for Conducting Comparative Effectiveness Reviews. We will apply evidence grades to the bodies of evidence about each approach comparison for each outcome. We will assess the strength of the study designs according to those which best control confounding, selection and information bias. We will assess the quality and consistency of the best available evidence, including assessment of limitations to individual study quality (using individual quality scores), consistency, directness, precision, and the magnitude of the effect.

We will classify evidence pertaining to Key Questions 1- 7 into four basic categories: (1) “high” grade (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of the effect); (2) “moderate” grade (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of the effect and may change the estimate); (3) “low” grade (indicating low confidence that the evidence reflects the true effect and further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate); and (4) “insufficient” grade (evidence is unavailable).

G. Assessing Applicability – Throughout the report, we will discuss the applicability of studies in terms of the degree to which the study population, interventions, outcomes, and settings are relevant to risks of childhood obesity or overweight. Many issues may affect the applicability such as the differences in study populations (eg, country, age, sex, ethnicity, socioeconomic status), settings (physical and social environments), study design (randomized intervention trials vs. natural experiments), intervention implementation (eg, intensity) and evaluation (how outcomes were assessed). We will take these contextual factors into consideration during data synthesis, and be cautious about generalizing conclusions to the wider populations.

V. References


22. Freedman DS, Mei Z, Srinivasan SR, Berenson GS, Dietz WH. Cardiovascular risk factors and excess adiposity among...


VI. Definition of Terms

1. Obesity is a medical condition in which excess body fat has accumulated to the extent that it may have an adverse effect on health. In children, often obesity is defined based on age-sex-specific 95th BMI percentiles, while overweight is defined based on the 85th percentile. Other references, such as percentiles of waist circumference and skinfold thickness, have also been used.

2. Consumer Health Informatics encompasses technologies focused on indirect, as opposed to face-to-face contact with patients as the primary users of health information. This includes web-, phone-, “smart-phone,” and video-based programs, games, and information storehouses.

3. Community-based and Environment-level interventions include those which result from policy, legislative, built environment, and economic/pricing/food subsidy interventions.

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School policies will be considered with the school-based interventions. Additionally, interventions that interacts with the community (a group of individuals who exist prior to the intervention and who share one or more common characteristics).32

4. **Primary-care based interventions** are those which are carried out in/through the offices of a primary care practitioner, a clinic, or other health care entity delivering primary health care to children. Note that school-based health care will be classified under school-based interventions. Note that primary care interventions which include a health informatics component will be classified under primary-care interventions.

5. **Child-care settings** are those in which non-parental/non-custodian delivered care is provided to children, generally outside the home. Note that school-based after-care programs will be classified under school-based interventions.

6. **Home-based interventions** are those which are carried out in/through the child’s home; for example through attempts to alter foods purchased for home use or family fitness.

VII. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VIII. Review of Key Questions

For all EPC reviews, key questions were reviewed and refined as needed by the EPC with input from Key Informants and the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed. In addition, the key questions were posted for public comment and finalized by the EPC after review of the comments.

IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform healthcare decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and do not review the report, except as given the opportunity to do so through the peer or public review mechanism.

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Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts comprise a multi-disciplinary group of clinical, content, and methodologic experts who provide input in defining populations, approaches, comparisons, or outcomes as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not conduct analysis of any kind or contribute to the writing of the report and do not review the report, except as given the opportunity to do so through the public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers will be invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

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XII. Role of the Funder:

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Appendix A.

MEDLINE search strategy via PubMed:

<table>
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<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
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<td>Weight</td>
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<td>Setting</td>
<td>Specific exclusions</td>
<td>Adult EX</td>
<td>Animal EX</td>
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<td>&quot;body mass index&quot;[mh]</td>
<td>Preventative[tiab]</td>
<td>Caregivers[tiab]</td>
<td>Orlistat[Supplementary Concept]</td>
<td>(child[mi]</td>
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<td>&quot;skinfold thickness&quot;[tiab]</td>
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<td>Fathers[tiab]</td>
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<td>Home[tiab]</td>
<td></td>
<td>paediatric[tiab])</td>
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Source: [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)
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| “boy scout”[tiab] |  |
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| “Girl scouts”[tiab] |  |
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| Church[tiab] |  |
| Community[tiab] |  |
| Communities[tiab] |  |
| Faith[tiab] |  |
| Garden[tiab] |  |
| Gardening[mh] |  |
| Mosque[tiab] |  |
| Neighborhood[tiab] |  |
| Neighborhoods[tiab] |  |
| Recreation[mh] |  |
| Recreation[tiab] |  |
| Synagogue[tiab] |  |
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| YWCA[tiab] |  |
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| “calorie labeling”[tiab] |  |
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| “socioeconomic factors”[mh] |  |
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"internet"[MeSH Terms]  
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